UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION MDL No. 2875

Honorable Robert B. Kugler, District Court Judge

This Document Relates to All Actions

CERTIFICATION OF ALEXIA R. BRANCATO

ALEXIA R. BRANCATO, being of full age, certifies as follows:

- 1. I am a partner at Kirkland & Ellis LLP, attorneys for Defendants Torrent Pharmaceuticals Ltd. and Torrent Pharma, Inc. (collectively "Torrent"). I make this Certification based on personal knowledge and in support of Torrent-Specific Motions *In Limine* for the TPP Trial.
- 2. Attached hereto as Exhibit 1 is a true and correct copy of TORRENT-MDL2875-00433346.
- 3. Attached hereto as Exhibit 2 is true and correct copy of relevant excerpts of the transcript of the deposition of Sushil Jaiswal, dated June 25, 2021.
- 4. Attached hereto as Exhibit 3 is a true and correct copy of TORRENT-MDL2875-00005763 TORRENT-MDL2875-00005764.

- 5. Attached hereto as Exhibit 4 is a true and correct copy of relevant excerpts of the Expert Report of Philip Russ, dated October 31, 2022.
- 6. Attached hereto as Exhibit 5 is a true and correct copy of relevant excerpts of the transcript of the deposition of Kelly Gegenheimer, dated April 14, 2021.
- 7. Attached hereto as Exhibit 6 is a true and correct copy of relevant excerpts of the transcript of the deposition of Sushil Jaiswal, dated June 4, 2021.
- 8. Attached hereto as Exhibit 7 is a true and correct copy of relevant excerpts of the transcript of the deposition of Dawn Chitty, dated May 13, 2021.
- 9. Attached hereto as Exhibit 8 is a true and correct copy of relevant excerpts of the transcript of the deposition of Jocelyn Rivera, dated February 22, 2021.
- 10. Attached hereto as Exhibit 9 is a true and correct copy of TORRENT-MDL2875-00090454 TORRENT-MDL2875-00090463.
- 11. Attached hereto as Exhibit 10 is a true and correct copy of relevant excerpts of the transcript of the deposition of Dhrumit Shah, dated March 16, 2021.
- 12. Attached hereto as Exhibit 11 is a true and correct copy of TORRENT-MDL2875-00072542.

- 13. Attached hereto as Exhibit 12 is a true and correct copy of TORRENT-MDL2875-00159677.
- 14. Attached hereto as Exhibit 13 is a true and correct copy of TORRENT-MDL2875-00099932 TORRENT-MDL2875-00099933.
- 15. Attached hereto as Exhibit 14 is a true and correct copy of TORRENT-MDL2875-00523107.
- 16. Attached hereto as Exhibit 15 is a true and correct copy of TORRENT-MDL2875-00523106.
- 17. Attached hereto as Exhibit 16 is a true and correct copy of TORRENT-MDL2875-00005188 TORRENT-MDL2875-00005191.
- 18. Attached hereto as Exhibit 17 is a true and correct copy of TORRENT-MDL2875-00087628 TORRENT-MDL2875-00087631.
- 19. Attached hereto as Exhibit 18 is a true and correct copy of TORRENT-MDL2875-00520737.
- 20. Attached hereto as Exhibit 19 is a true and correct copy of the FDA Company Announcement, dated August 17, 2018, titled "Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Valsartan/Amlodipine/HCTZ Tablets," available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-

alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-valsartan-amlodipine-hctz-tablets.

- 21. Attached hereto as Exhibit 20 is a true and correct copy of relevant excerpts of the Amended Expert Report of Ali Afnan, Ph.D., dated January 11, 2023.
- 22. Attached hereto as Exhibit 21 is a true and correct copy of an FDA publication, dated January 28, 2019, titled "Combined N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) Impurity Assay by GC/MS-Headspace" available at https://www.fda.gov/media/117843/download.
- 23. Attached hereto as Exhibit 22 is a true and correct copy of TORRENT-MDL2875-00072713 TORRENT-MDL2875-00072716.
- 24. Attached hereto as Exhibit 23 is a true and correct copy of TORRENT-MDL2875-00142942 TORRENT-MDL2875-00142947.
- 25. Attached hereto as Exhibit 24 is a true and correct copy of relevant excerpts of the transcript of the deposition of Akhilesh Nagaich, dated February 9, 2023.
- 26. Attached hereto as Exhibit 25 is a true and correct copy of FDA Guidance, dated March, 2020, titled "Product Recalls, Including Removals and Corrections: Guidance for Industry" available at https://www.fda.gov/regulatory-

information/search-fda-guidance-documents/product-recalls-including-removals-and-corrections.

- 27. Attached hereto as Exhibit 26 is a true and correct copy of TORRENT-MDL2875-00124209 TORRENT-MDL2875-00124211.
- 28. Attached hereto as Exhibit 27 is a true and correct copy of relevant excerpts of the transcript of the deposition of Philip Russ, dated January 5, 2023
- 29. Attached hereto as Exhibit 28 is a true and correct copy of the transcript of the deposition of Kalpeshkumar Patel, dated June 3, 2021
- 30. Attached hereto as Exhibit 29 is a true and correct copy of relevant excerpts of the transcript of the deposition of Sushil Jaiswal, dated June 5-6, 2021.

Dated: February 16, 2024

Respectfully submitted,

/s/Alexia R. Brancato

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Attorneys for Torrent Pharmaceuticals Ltd.

CERTIFICATE OF SERVICE

I, Alexia R. Brancato, an attorney, hereby certify that on February 16, 2024, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF, and caused it, along with any documents filed under seal, to be served on all counsel of record by email.

By: /s/Alexia r. Brancato

Alexia R. Brancato